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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/737,324

12/16/2003

Edward H. Cully

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5934

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

02/17/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/737,324	<b>Applicant(s)</b> CULLY ET AL.	
	<b>Examiner</b> William H. Matthews (Howie)	<b>Art Unit</b> 3774	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 November 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-13,15-19,21,25-28,35 and 36 is/are pending in the application.
- 4a) Of the above claim(s) 1,3-13,15-19,21 and 25-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35,36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11-13-09</u>  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Response to Arguments***

Applicant's arguments with respect to claims 1 and 35-36 have been considered but are not persuasive.

Applicant argues the "preferred graft material" is ePTFE, and ePTFE is readily known to be anisotropic in the absence of an otherwise teaching, therefore the embodiment of Figure 4B would be considered to include anisotropic ePTFE graft material by one of ordinary skill.

Examiner disagrees because, initially, the elected species of figure 4B, clearly discloses splitting *due* to the perforation pattern. The specification does not disclose this embodiment to include anisotropic material, and therefore does not contemplate whether the anisotropic material itself, or perforations in the material, would provide the primary splitting ability. While the specification provides support for *preferably* using ePTFE, it does not require the *preferred* ePTFE to be anisotropic and cause splitting upon a tension force in any embodiment except the non-elected species of figure 4C (which lacks perforations). Applicant has not suggested how it would be obvious to an ordinary artisan, upon reading the specification, to select a particular anisotropic ePTFE incorporated by reference in USPN 3,953,566 and add the perforations in a number and diameter such that tension applied to the graft causes splitting at the weakened regions of the anisotropic material rather than the perforations, as claimed. This is because the perforations would have no function, and be unnecessary, if the material is designed to split apart on its own, based on the specification. In addition, as the specification lacks

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any phrase(s) describing the combination of perforated graft material and anisotropic graft material, the specification suggests the inventor's did not contemplate the combination as a critical feature of the invention.

Examiner reminds Applicant that a similar rejection was applied to claims 23-24 in the office action mailed 5/15/08, and followed by cancellation of said claims. Thus it is unclear why Applicant has reintroduced similar subject matter.

### ***Election/Restrictions***

Claims 1,3-13,15-19,21,25-28 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention (Figure 4C described at page 11 lines 1-23 of applicant's specification), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4-6-05.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 35-36 appear directed to the elected

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species of figure 4B and described at page 10 lines 30-36, however they depend from claim 1 which is directed to figure 4C. The specification as originally filed failed to disclose an embodiment combining the features of perforations or patterns extending through only a portion of the graft material, in combination with anisotropic material, as claimed.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/  
Primary Examiner  
Art Unit 3774